



COVID-19

Lab Reporting Guidance

Variant Reporting Guidance

Regulatory Position on Reporting Sequencing Results to Public Health Departments

The [Centers for Medicare and Medicaid Services](#) (CMS) published information that allows both non-CLIA Clinical Laboratory Improvement Amendments (CLIA) and CLIA-certified facilities that perform SARS-CoV-2 genetic sequencing on identified specimens to report patient-specific results to state, local, tribal, or territorial public health departments. Any sequencing data can be reported to public health.

Laboratories can only report results to patients or providers when sequencing is performed in a CLIA certified laboratory and in CLIA-compliant manner. This means sequencing was performed in compliance with all applicable CLIA regulations, in addition to the laboratory obtaining a CLIA certificate. Not all laboratories perform SARS-CoV-2 genetic sequencing in a CLIA-compliant manner, as it is only necessary if results are intended to be used for the purposes of a person's diagnosis, prevention, treatment, or health assessment, and reported to the patient or provider. SARS-CoV-2 genetic sequencing results reported to public health do not have to be performed in a CLIA-compliant manner as reporting is for surveillance and public health purposes only.

Both scenarios require reporting to the Tennessee Department of Health (TDH) if the patient is a resident of Tennessee, regardless of where they were tested, or the specimen was obtained. Tennessee further requires the reporting of all results for specimens submitted by ordering providers in Tennessee regardless of the patient address.

How to Report SARS-CoV-2 Sequencing Results to the Tennessee Department of Health

This guidance outlines the process for adding a SARS-CoV-2 genetic sequencing result to an existing electronic laboratory report to provide that information to TDH as well as guidance for those who are currently reporting results via our Emergency Use Template (EUT). If you are not currently reporting via either of these methods, please contact ceds.informatics@tn.gov to discuss set up. SARS-CoV-2 sequencing results should be reported as a follow-up to the original positive viral test result. The electronic reporting of the sequencing data should include all the original patient demographic data, along with both the viral test report content and the second ordered test with viral genetic lineage identified. CDC requests that laboratories and facilities that have SARS-CoV-2 positive specimens and intend to report -CoV-2 lineages, including variants, should upload sequence data to a public database (National Center for Biotechnology

Technical Guidance for ELR Reporting of Sequencing Results to the Tennessee Department of Health

The table below provides detailed guidance on reporting SARS-CoV-2 sequencing results to TDH and includes examples for packaging data elements. This technical guidance is **subject to change as new information becomes available about the impact of SARS-CoV-2 evolution on public health**. For simplicity, only the fields needing more guidance in the additional observations for the variant lineage and the ID for the sequence sample are highlighted here. Other data elements normally part of each Observation/Result Segment (OBX), such as the result date, still need to be packaged as well.

#	Data Element	Reporting Requirement			Technical Specifications	Notes	Example	HL7 Field
		Federal / CDC / HHS	State / Local PHD	Ordering Provider / EHR				
2	Test result (performed)	Yes	Yes	Requested	Must use harmonized LOINC codes , when available	Variant identified through sequencing isolate from the original specimen	LOINC: 96741-4: SARS-CoV-2 (COVID-19) variant [Type] in Specimen by Sequencing	OBX-3
	Test result (values)				Qualitative tests: Must use harmonized SNOMED-CT or PLR value set codes when available		OBX-2= Preferred CWE but can accept ST PLR or SNOMED-CT Values ¹ These are simply examples of current PLR codes. Please see the footnote below for current lists of codes. PLR4366^SARS-CoV-2 B.1.1.7 lineage^PLR PLR4367^SARS-CoV-2 B.1.351 lineage^PLR PLR4371^SARS-CoV-2 B.1.427 lineage^PLR PLR4369^SARS-CoV-2 B.1.429 lineage^PLR PLR4401^SARS-CoV-2 B.1.525 lineage^PLR PLR4370^SARS-CoV-2 B.1.526 lineage^PLR PLR4402^SARS-CoV-2 B.1.526.1 lineage^PLR PLR4368^SARS-CoV-2 P.1 lineage^PLR PLR4372^SARS-CoV-2 P.2 lineage^PLR PLR4404^SARS-CoV-2 lineage of unknown significance^PLR	
3	Test result date	Yes	Yes	Requested	YYYY[MM[DD]]	Date the test result was obtained	Example: 20200716	OBX-19.1
7	Device Identifier	Yes	Yes	Requested	Must use harmonized Device Identifiers , when	Manufacturer requests UDI issuanceexter	Example DI: 01234567891011 Example Trade Name:	OBX-17 , OBX-18

¹ PLR and SNOMED values should be updated as new codes are defined and added to the Confluence site at

<https://confluence.hl7.org/display/OO/Proposed+HHS+ELR+Submission+Guidance+using+HL7+v2+Messages?focusedCommentId=86968216>

					available . The DI is contained within the UDI, created by manufacturer	nal icon , then provides DI, or pull from GUDID databaseexternal icon If DIs unavailable: Use the Unique Trade Name (controlled under 21 CFR 209.10(b)(1)external icon)	SARS-CoV-2 Test_Company_MNT^^99ELR	
9	Sequence ID	Yes	Requested		Lab assigned Sequence ID	Add as an additional observation to the original report	PLT2397^Filler Lab Assigned Genetic Sequence Identifier^PLT OBX-2 = Preferred CX but can accept ST <WHATEVER FORMAT THE LAB USES>	OBX-3 OBX-2 OBX-5
19	Performing facility name; CLIA #	Yes; if known	Yes; if known		Alpha; ##D#####	CLIA Laboratory Search	Example: 21D1234567	OBX-23.10

Acronyms:

CDC: Centers for Disease Control and Prevention

CLIA: Clinical Laboratory Improvement Amendments

DI: Device Identifier

EHR: Electronic Health Record

GUDID: Global Unique Device Identification Database

HHS: Department of Health and Human Services

HL7: Health-Level Seven

ID: Identifier

LIVD: LOINC In Vitro Diagnostic

LOINC: Logical Observations Identifiers Names and Codes

NPI: National Provider Identifier

NPPES: National Plan and Provider Enumeration System

OBR: Observation Request Segment

OBX: Observation/Result Segment

OMB: Office of Management and Budget

ORC: Common Order Segment

PHD: Public Health Department

PID: Patient Identification Segment

SNOMED-CT: Systematized Nomenclature of Medicine – Clinical Terms

Example messages

1. Include prior PCR result that resulted in decision to do sequencing, if performed at the same lab (**Parent-child linking, if possible**)

MSH|...

SFT|...

PID|1|...

ORC|RE||425195^<FillerSystem>^<OID>^ISO|||||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|||20201103093552-0500||||||HealthCare|301 Anystreet^^Daytona Beach^FL^32117|^PRN^PH^^111^1234566|

OBR|1||425195^<FillerSystem>^<OID>^ISO |94500-6^SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection^LN^^^^2.69|||20201102063552-0500|||||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|||||||20201103093827-0500|||F

OBX|1|CWE|94500-6^SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection^LN^^^^2.69|||260373001^Detected^SCT^^^^Vunknown|||||F||||<CLIA>|Abbott RealTime SARS-CoV-2 assay_Abbott Molecular Inc._EUA^^99ELR^^^^Vunknown|||20201103093827-0500||||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^<CLIA>|2110 Any Road^^Nashville^TN^37011

NTE|1|L|Abbott RealTime SARS-CoV-2 assay_Abbott Molecular Inc._EUA|RE^Remark^HL70364^^^^2.5.1

OBX|2|NM|30525-0^Age^LN^^^^2.68||40|a^year^UCUM^^^^Vunknown|||||F||||<CLIA>|||20201103093827-0500||||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^<CLIA>|2110 Any Road^^Nashville^TN^37011||||QST

OBX|3|CWE|95419-8^Whether patient has symptoms related to condition of interest^LN^^^^2.69-pre||Y^Yes^HL70136^^^^2.5.1|||||F||||<CLIA>|||20201103093827-0500||||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^<CLIA>|2110 Any Road^^Nashville^TN^37011||||QST

OBX|4|CWE|82810-3^Pregnancy status^LN^^^^2.68||60001007^Not Pregnant^SCT^^^^Vunknown|||||F||||<CLIA>|||20201103093827-0500||||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^<CLIA>|2110 Any Road^^Nashville^TN^37011||||QST

SPM|1|^MOL20-003999&NEOLINK.STAG&2.16.840.1.113883.3.8589.4.2.29.2&ISO|258529004^Throat swab^SCT^^^^Vunknown|||||||||||20201102063552-0500|20201103063552-0500

ORC|RE||425197^<FillerSystem>^<OID>^ISO|||||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|||20201103093552-0500|||||HealthCare|301 Anystreet^^Daytona Beach^FL^32117|^PRN^PH^^111^1234566|

OBR|2||425197^<FillerSystem>^<OID>^ISO|96741-4^SARS-CoV-2 (COVID-19) variant [Type] in Specimen by Sequencing^LN^^^^2.69|||20201104093827-

0500|||||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|||||20201103093827-0500|||F|94500-6&SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection&LN^^Detected|||^425197&<FillerSystem>&<OID>&ISO

OBX|1|CWE|96741-4^SARS-CoV-2 (COVID-19) variant [Type] in Specimen by Sequencing^LN^^^^2.69||PLR4366^ SARS-CoV-2 variant B.1.1.7 (501Y.V1)^PLR^^^^1.35|||||F||||<CLIA>|||20201104093827-0500|||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^<CLIA>|2110 Any Road^^Nashville^TN^37011

OBX|2|CX|96766-1^GISAID sequence accession number^LN||EPI ISL 250390^^ GISAID.DB.STAGPROD 2.16.840.1.113883.3.8589.4.2.64.2&ISO^ACSN|||||F||||<CLIA>|||20201104093827-0500|||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^<CLIA>|2110 Any Road^^Nashville^TN^37011

SPM|1|^MOL20-003999&NEOLINK.STAG&2.16.840.1.113883.3.8589.4.2.29.2&ISO|258529004^Throat swab^SCT^^^Vunknown|||||||||20201102063552-0500|20201103063552-0500

2. Include prior PCR result that resulted in decision to do sequencing, if performed at the same lab – no parent-child linkage

MSH|...

SFT|...

PID|1|...

ORC|RE||425195^<FillerSystem>^<OID>^ISO|||||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|||20201103093552-0500|||||HealthCare|301 Anystreet^^Daytona Beach^FL^32117|^PRN^PH^^111^1234566|

OBR|1||425195^<FillerSystem>^<OID>^ISO|94500-6^SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection^LN^^^^2.69|||20201102063552-0500|||||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|||||20201103093827-0500|||F

OBX|1|CWE|94500-6^SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection^LN^^^^2.69||260373001^Detected^SCT^^^Vunknown|||||F|||<CLIA>|Abbott RealTime SARS-CoV-2 assay_Abbott Molecular Inc._EUA^^99ELR^^^Vunknown||20201103093827-0500|||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^<CLIA>|2110 Any Road^^Nashville^TN^37011

NTE|1|L|Abbott RealTime SARS-CoV-2 assay_Abbott Molecular Inc._EUA|RE^Remark^HL70364^^^^2.5.1

OBX|2|NM|30525-0^Age^LN^^^^2.68||40|a^year^UCUM^^^Vunknown|||||F|||<CLIA>|||20201103093827-0500|||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^<CLIA>|2110 Any Road^^Nashville^TN^37011||||QST

OBX|3|CWE|95419-8^Whether patient has symptoms related to condition of interest^LN^^^^2.69-pre||Y^Yes^HL70136^^^^2.5.1|||||F||||<CLIA>||||20201103093827-0500||||Testinglab
 name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^<CLIA>|2110 Any Road^^Nashville^TN^37011||||QST

OBX|4|CWE|82810-3^Pregnancy status^LN^^^^2.68|60001007^Not Pregnant^SCT^^^^Vunknown|||||F||||<CLIA>||||20201103093827-0500||||Testinglab
 name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^<CLIA>|2110 Any Road^^Nashville^TN^37011||||QST

SPM|1|^MOL20-003999&NEOLINK.STAG&2.16.840.1.113883.3.8589.4.2.29.2&ISO||258529004^Throat
 swab^SCT^^^^Vunknown|||||||||20201102063552-0500|20201103063552-0500

ORC|RE||425197^<FillerSystem>^<OID>^ISO|||||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^NPI|||20201103093552-0500|||||HealthCare|301 Anystreet^^Daytona Beach^FL^32117|^PRN^PH^^111^1234566|

OBR|2||425197^<FillerSystem>^<OID>^ISO|96741-4^SARS-CoV-2 (COVID-19) variant [Type] in Specimen by Sequencing^LN^^^^2.69|||20201104093827-0500|||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^NPI|||20201103093827-0500|||F|94500-6&SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection&LN^^Detected|||^425197&<FillerSystem>&<OID>&ISO

OBX|1|CWE|96741-4^SARS-CoV-2 (COVID-19) variant [Type] in Specimen by Sequencing^LN^^^^2.69||PLR4366^ SARS-CoV-2 variant B.1.1.7 (501Y.V1)^PLR^^^^1.35|||||F||||<CLIA>||||20201104093827-0500||||Testinglab
 name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^<CLIA>|2110 Any Road^^Nashville^TN^37011

OBX|2|CX|96766-1^GISAID sequence accession number^LN||EPI ISL 250390^^ GISAID.DB.STAGPROD
 2.16.840.1.113883.3.8589.4.2.64.2&ISO^ACSN|||||F||||<CLIA>||||20201104093827-0500||||Testinglab
 name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^<CLIA>|2110 Any Road^^Nashville^TN^37011

SPM|1|^MOL20-003999&NEOLINK.STAG&2.16.840.1.113883.3.8589.4.2.29.2&ISO||258529004^Throat
 swab^SCT^^^^Vunknown|||||||||20201102063552-0500|20201103063552-0500

3. Just the variant identification sent as ST datatype if CWE is not possible (with reference to the GSAID sequence as an option)

MSH|...

SFT|...

PID|1|...

ORC|RE||425197^<FillerSystem>^<OID>^ISO|||||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^NPI|||20201103093552-0500|||||HealthCare|301 Anystreet^^Daytona Beach^FL^32117|^PRN^PH^^111^1234566|

OBR|1||425197^<FillerSystem>^<OID>^ISO|96741-4^SARS-CoV-2 (COVID-19) variant [Type] in Specimen by Sequencing^LN^^^^2.69|||20201104093827-0500|||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^NPI|||20201103093827-0500|||F

OBX|1|CWE|96741-4^SARS-CoV-2 (COVID-19) variant [Type] in Specimen by Sequencing^LN^^^^2.69||PLR4366^ SARS-CoV-2 variant B.1.1.7
 (501Y.V1)^PLR^^^^1.35|||||F||||<CLIA>||||20201104093827-0500|||Testinglab
 name^L^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^<CLIA>|2110 Any Road^^Nashville^TN^37011

OBX|2|ST|96766-1^GISAID sequence accession number^LN||EPI ISL 250390||||F||||<CLIA>|||20201104093827-0500|||Testinglab
 name^L^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^<CLIA>|2110 Any Road^^Nashville^TN^37011

SPM|1|^MOL20-003999&NEOLINK.STAG&2.16.840.1.113883.3.8589.4.2.29.2&ISO||258529004^Throat
 swab^SCT^^^Vunknown|||||||||20201102063552-0500|20201103063552-0500

Technical Guidance for Reporting Sequencing Results to the Tennessee Department of Health using Emergency Use Template

The table below provides detailed guidance on reporting SARS-CoV-2 sequencing results to TDH via the Emergency Use Template (EUT) and includes examples for data elements. This technical guidance is **subject to change as new information becomes available about the impact of SARS-CoV-2 evolution on public health**. For simplicity, only the fields needing more guidance in the additional observations for the variant lineage and the ID for the sequence sample are highlighted here. Other data elements normally part of each result still need to be included as well.

#	Data Element	Reporting Requirement			Technical Specifications	Notes	Example
		Federal / CDC / HHS	State / Local PHD	Ordering Provider / EHR			
2	TestName	Yes	Yes	Requested	Must use harmonized LOINC codes , when available	Variant identified through sequencing isolate from the original specimen	LOINC: 96741-4: SARS-CoV-2 (COVID-19) variant [Type] in Specimen by Sequencing
	Result				Qualitative tests: Must use harmonized SNOMED-CT value set codes		The below are examples of current variant names. Please see the footnote below ² for where to get a list of variants. SARS-CoV-2 B.1.1.7 lineage SARS-CoV-2 B.1.351 lineage SARS-CoV-2 B.1.427 lineage SARS-CoV-2 B.1.429 lineage SARS-CoV-2 B.1.525 lineage SARS-CoV-2 B.1.526 lineage SARS-CoV-2 B.1.526.1 lineage SARS-CoV-2 P.1 lineage

² PLR and SNOMED values should be updated as new codes are defined and added to the Confluence site at <https://confluence.hl7.org/display/OO/Proposed+HHS+ELR+Submission+Guidance+using+HL7+v2+Messages?focusedCommentId=86968216>

						SARS-CoV-2 P.2 lineage SARS-CoV-2 lineage of unknown significance
3	DateVerified	Yes	Yes	Requested	mm/dd/yyyy or mm/dd/yyyy hh:mm:ss	Date of testing Example: 05/10/2021 13:54
9	Sequence ID	Yes	Requested		Lab assigned Sequence ID	Please reach out to cds.informatics@tn.gov to discuss options for sending this field specific to your organization.